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#### **REMARKS**

Claims 1-20 and 25-32 are pending in the application.

Claims 1, 3, 4, 7-9, 21-24, 29-31, and 33 are canceled.

Claims 2, 10-12, 14, 17, 19, 20, 25-28, and 32 are currently amended.

Claims 5, 6, 13, 15, 16, and 18 are original.

Claims 34 and 35 are new.

Claims 2, 5, 6, 10-20, 25-28, 32, 34, and 35 would be all of the claims pending in the application if the instant amendment is entered.

## **Discussion of Amendments**

Claim 2 is currently amended to delete the term "neuropathic pain" and add the terms "crush injury, constriction injury, burn pain, gout, trigeminal neuralgia, causalgia, plexus avulsion, limb amputation." Certain claims are also currently amended to change the dependencies from claim 1 to claim 2, as claim 1 is canceled. Claims 27, 28, and 32 are currently amended to delete non-elected subject matter and claims 29-31 are canceled for being drawn to non-elected subject matter.

## Double Patenting Rejection

Claims 1 to 20 and 25 to 32 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 22 to 42 of Barrett et al., U.S. Patent No. 6,545,030 ('030 patent). It was mentioned in the Office Action that claims 22 to 42 of the '030 patent teach the compounds of instant claims 1 to 20 and 25 to 32 and methods for treating, among others, cancer, stroke, or a complication of diabetes. Although claims 22 to 42 of the '030 patent are not identical to the instant claims, it was alleged in the Office Action that they are not patentably distinct from each other. In the Office Action, it was mentioned that many of the cancer patients, stroke patients, or patients with a complication of diabetes suffer neuropathic pain and therefore practicing the claims in the '030 patent would effectively practice the instant claimed invention method.

Applicants respectfully traverse the rejection because claims 1, 3, 4, 7-9, and 29-31 are canceled, rendering the rejection of claims 1, 3, 4, 7-9, and 29-31 moot, and because Applicants believe that the invention of instant claims 2, 5, 6, 10-20, 25-28, and 32, and for that matter new claims 34 and 35, is patentably distinct from the invention of claims 22 to 42 of the '030 patent.

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Claims 22 to 39 of the '030 patent are directed to methods of:

treating a proliferative disease;

treating a proliferative disease selected from psoriasis, restenosis, autoimmune disease, and atherosclerosis;

treating cancer;

treating MEK-related cancer;

treating cancer wherein the cancer is brain, breast, ovarian, pancreatic, prostate, renal, or colorectal cancer;

treating or ameliorating the sequelae of stroke;

treating or ameliorating the sequelae of heart failure;

treating or reducing the symptoms of xenograft rejection in an organ transplant, limb transplant, skin transplant, cell(s) transplant, or bone marrow transplant patient;

treating osteoarthritis;

treating rheumatoid arthritis;

treating cystic fibrosis;

treating hepatomegaly;

treating cardiomegaly:

treating Alzheimer's disease;

treating a complication of diabetes;

treating septic shock;

treating a viral infection; or

treating a viral infection wherein the infection is an infection of HIV, respectively. Claims 40-42 of the '030 patent are directed to a method of: treating cancer in a patient, wherein the patient is also administered radiation therapy or chemotherapy; the method wherein chemotherapy comprises a mitotic inhibitor; or the method wherein the mitotic inhibitor is selected from paclitaxel, docetaxel, vincristine, vinblastine, vinorelbine, and vinflunine, respectively.

It is Applicants' belief that in the Office Action a *prima facie* association has not been established between the methods for treating taught in claims 20 to 42 of the '030 patent and the instant method of treating chronic pain selected from idiopathic pain and pain associated with crush injury, constriction injury, burn pain, gout, trigeminal neuralgia, causalgia, plexus avulsion, limb amputation, chronic alcoholism, vitamin deficiency, uremia, or hypothyroidism. The rejection specifically alleged a connection between cancer, stroke, or complications from diabetes and neuropathic pain. Further, on page 4

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of the Office Action (in the § 102(e) rejection), a connection was alleged between arthritis and neuropathic pain associated with arthritis. However, Applicants do not find in the Office Action any connection between the methods for treating taught in claims 20 to 42 of the '030 patent and the method of treating chronic pain in instant claims 2, 5, 6, 10-20, 25-28, and 32, and for that matter new claims 34 and 35.

Further, Applicants believe that the instant claimed method of treating chronic pain is not an obvious variation of the methods for treating taught in claims 20 to 42 of the '030 patent. Agreeing, it was stated on page 4 of the Office Action that treating pain as herein claimed is not an obvious variation of treating arthritis, cancer, stroke, etc. as claimed in the '030 patent.

In view of the above remarks, Applicants believe that claims 2, 5, 6, 10-20, 25-28, and 32, and for that matter new claims 34 and 35, are patentable under the judicially created doctrine of obviousness-type double patenting.

# Claim Rejections 35 U.S.C. § 102

Claims 1 to 20 and 25 to 32 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Barrett et al., U.S. Patent No. 6,545,030 ('030 patent). It was mentioned in the Office Action that the '030 patent teaches the compounds of instant claims 1 to 20 and 25 to 32 and methods for treating, among others, cancer, stroke, or a complication of diabetes. In the Office Action, it was alleged that practicing the methods for treating cancer, stroke, or a complication of diabetes taught in the '030 patent would inherently treat neuropathic pain associated with cancer, stroke, or a complication of diabetes.

Applicants respectfully traverse the rejection because claims 1, 3, 4, 7-9, and 29-31 are canceled, rendering the rejection of claims 1, 3, 4, 7-9, and 29-31 moot, and because Applicants believe that the invention of instant claims 2, 5, 6, 10-20, 25-28, and 32, and for that matter new claims 34 and 35, is not inherently anticipated by the '030 patent.

The U.S. Court of Appeals for the Federal Circuit recently reiterated the standards for anticipation by inherency:

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"A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Lewmar Marine, Inc. v. Barient Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991)." {emphasis and italics in original; Smithkline Beecham Corporation and Beecham Group, P.L.C. v. Apotex Corp., Apotex, Inc., and Torpharm, Inc., 403 F.3d 1331; 74 USPQ2d 1396 (Fed. Cir. 2005)}.

It is Applicants' belief that the Office Action has not established a *prima facie* §102(e) rejection because the Office Action did not show that an instant invention characteristic is necessarily present in the methods for treating taught in the '030 patent, wherein the instant characteristic is treating chronic pain selected from idiopathic pain and pain associated with crush injury, constriction injury, burn pain, gout, trigeminal neuralgia, causalgia, plexus avulsion, limb amputation, chronic alcoholism, vitamin deficiency, uremia, or hypothyroidism.

In view of the above remarks, Applicants believe that claims 2, 5, 6, 10-20, 25-28, and 32, and for that matter new claims 34 and 35, are not anticipated by the '030 patent and are patentable under 35 U.S.C. § 102(e).

# Information Disclosure Statement

Applicants make available to the Patent and Trademark Office an Information Disclosure Statement on forms PTO/SB/08A and/or PTO/SB/08B and a copy of the art cited thereon. Applicants respectfully request that the Examiner consider carefully the complete text of the cited reference(s) in connection with the continued examination of the above-identified application in accord with 37 CFR §1.104(a). It is respectfully requested that all cited reference(s) considered by the Examiner be listed in the "References Cited" section of any patent issuing from the present application.

## Conclusion

Applicants believe that it has not been shown in the Office Action that practicing the methods for treating taught in the '030 patent would effectively practice the method of treating chronic pain of instant claims 2, 5, 6, 10-20, 25-28, and 32, and for that matter new claims 34 and 35. In view of the above amendments and remarks, Applicants believe that the rejections of claims 1 to 20 and 25 to 32 are overcome. Applicants

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request reconsideration and allowance of claims 2, 5, 6, 10-20, 25-28, and 32, and consideration and allowance of new claims 34, and 35.

Respectfully submitted,

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